Va. DMHMRSAS Pharmacy, Therapeutics Formulary Committee

I. Community Resource Pharmacy (CRP) Formulary Management

GENERAL PRINCIPLES
Medications are categorized according to Pharmacologic Therapeutic Classifications. The numerical indications that correlate with the classification will be available and can be directly referenced to standard reference resources such as the American Hospital Formulary Service, First Data Bank publication[s], Physicians Desk Reference and or the FDA website.

In general, it is our goal that drugs within a given drug class will be included in the formulary based on their having significant value in terms of their efficacy, safety, pharmacodynamics, pharmacokinetics, sites of action and side effect profiles.

Final Actions/Recommendations

A. FORMULARY ADDITION CRITERIA
The following factors will be considered when specific drugs or drug classes are reviewed for Formulary inclusion:

1. EFFICACY, EFFECTIVENESS AND SAFETY
The most important consideration in determining whether a drug product can be added to the formulary is the compound's efficacy and safety. The assessment of efficacy and safety is based on an objective evaluation of published data and the experience of clinical staff. This includes information from the following areas:

- Pharmacodynamic and pharmacokinetic data such as drug absorption, metabolism, excretion, Cytochrome P450 System, and half-life.
- Risks such as potential to cause a sentinel event, abuse, medication error, “look alike / sound alike” errors.
- Pharmacoeconomic data such as cost effectiveness in comparison to similar and readily available products.

2. DOSING INTERVAL AND SIDE EFFECT PROFILE
Some agents are preferred over others because of less frequent dosing intervals and fewer side effects. Patient compliance depends in large part on the frequency with which a drug must be administered and the severity of side effects. Frequent dosing of medications may result in greater demands on pharmacy (e.g., increased costs for supplies and transport) and the patient, which may lead to noncompliance.

3. COST

Community Resource Pharmacy, Attn: Pharmacy Manager; Box 4030, Petersburg, VA. 23803. Send inquiries to Central Office, Attention: Medical Director / Clinical Pharmacy Services; fax (804) 786-8623, Va. DMHMRSAS or Mail: Medical Director / Clinical Pharmacy Services, DMHMRSAS; Jefferson Bldg; 1220 Bank Street, Richmond, VA. 23220

The impact of cost on a drug's inclusion in the formulary is an important consideration. This factor is of particular importance when comparing several drugs within the same therapeutic class. Although cost is an important issue, providing high quality patient care remains the highest priority and will not be compromised by cost considerations.

4. AVAILABILITY OF ALTERNATIVE DRUGS
Any drug added to the Formulary must have advantages in efficacy and safety, dosing interval and side-effect profile, or cost. An alternative drug can often be deleted when a more effective drug is added.

5. RECOMMENDATIONS OF CLINICAL STAFF
The Committee shall solicit the advice and recommendations of clinical consultants, if needed, on the usefulness of specific drugs. The principal role of these individuals is to assist Committee members to understand the clinical circumstances in which a drug may be useful, and to address the relevant literature. Decisions are based primarily on objective evaluation of published data, rather than the anecdotal experiences of individual physicians.

6. LOOK-ALIKE/SOUND-ALIKE CRITERIA
Consideration will be given to look-alike / sound-alike criteria in selecting formulary drug in order to avoid the potential for medication errors.

There will be a template utilized for all formulary additions that will include the data above.

B. GUIDELINES FOR USING THE NON- FORMULARY DRUG REQUEST

1. A physician requesting a non-formulary medication must fill out a Non-Formulary Drug Request for each individual patient / client.

2. The requesting physician will send the request to the Pharmacy for initial review and evaluation, (appropriately filled out, etc.)

3. If the CRP Pharmacy Director / Manager deems the request is therapeutically justified, the medication will be ordered and supplied for thirty days and or until the next PTF Clinical Services Sub-Committee meeting for review and addition (See Formulary Management, Formulary addition criteria) if within a reasonable amount of time.

4. A copy of all Non-Formulary Drug Requests will be sent to the PTF Clinical Services Sub-Committee Chair and to the Department's psychopharmacologist by the Pharmacy Director / Manager within 15 days of receiving the request.

5. If the Pharmacy Director / Manager feels that further evaluation is immediately necessary, they will forward the Non-Formulary Request with Pharmacy comments and or concerns to PTF Clinical Services Sub-Committee Chair and the Department's psychopharmacologist.

6. If the request is approved by the PTF Clinical Services Sub-Committee Chair, the Department's psychopharmacologist, and or the PTF Clinical Services Sub-Committee, the medication will be ordered by the Pharmacy for a period not to exceed six months without further review / action, (see steps 8 – 11 below).

7. If the request is denied, the Pharmacy Director / Manager will notify the requesting clinician.

8. The non-formulary medication will be ordered when the approved request AND the physician's order for the medication are received by the pharmacy.

9. The PTF Clinical Services Sub-Committee will, as an internal control mechanism, review all Non-Formulary Drug Requests at their regular meetings.

10. If a non-formulary medication is restarted after 30 days of the initial Non-Formulary Drug Request Form, a new Non-Formulary Drug Request will be requested.

11. PTF Clinical Services Sub-Committee will monitor all non-formulary drugs for length of treatment and by the Director / Manager of the Community Resource Pharmacy for the Community Resource Pharmacy clientele. In the future, Drug Utilization Evaluations may be requested by the PTF Clinical Services Sub-Committee and made to the CRP Manager for non-formulary medications being used for more than 6 months time.

C. Guidelines for Additions/Deletions To The Statewide Formulary

1. Criteria for inclusion of a drug are explained in the Formulary Management Criteria section of the Statewide Formulary.

2. Any State facility physician / pharmacist and or Community Services Board physician / pharmacist may request a drug or preparation be added to or deleted from the Statewide Formulary, (please include an address for response). *The PTF Clinical Services Sub-Committee prefers to have petitioners for formulary addition utilize the non-formulary process prior to requesting any addition to the formulary.*

3. A Request for Addition / Deletion to the Statewide Formulary Form must be submitted to the PTF Clinical Services Sub-Committee for evaluation and approval. Requesting clinicians will send the request to the Pharmacy for initial review and evaluation, (appropriately filled out, etc.).

4. A copy of all requests for Formulary Additions / Deletions will be sent to the PTF Clinical Services Sub-Committee Chair and to the Department's psychopharmacologist by the Pharmacy Director / Manager within 30 days of receiving the request.

5. The PTF Clinical Services Sub-Committee Chairperson (or designee) must complete and sign the Request Form in the designated area noting receipt.

6. The completed Request Form must be submitted to the DMHMRSAS CRP Pharmacy, Therapeutics & Formulary (PT&F) Committee for review within ninety days of receipt.

7. If the request is approved by the PTF Clinical Services Sub-Committee Chair, the Department's psychopharmacologist, and or the PTF Clinical Services Sub-Committee, the medication will be ordered by the Pharmacy and be maintained under normal controls as other formulary medications. The Pharmacy Director / Manager will notify the requesting clinician and CRP accounts, (i.e., Community Services Boards) of the formulary addition.

8. If the request is denied, the Pharmacy Director / Manager will notify the requesting clinician.

D. THERAPEUTIC SUBSTITION POLICY

Therapeutic Interchange is the selection of a chemically different drug that is from the same therapeutic class and has the same pharmacodynamic properties and pharmacotherapeutic outcomes of the originally prescribed medication. The concept of Therapeutic Interchange is consistent with current standards of accepted pharmacy and medical practice and is developed by the DMHMRSAS CRP Pharmacy, Therapeutics and Formulary (PT&F) Committee.

Therapeutic Interchange must occur within the following process:

1. The concept of a Therapeutic Interchange (TI) must be approved by the DMHMRSAS CRP PT&F Committee, the Medical Director of the DMHMRSAS (or designee) and the Pharmacy Director / Manager at the CRP.

2. Therapeutic Interchange must be clearly defined and incorporated into the DMHMRSAS CRP State Formulary and ideally, within the local facility Formularies. This information must be clearly disseminated to the medical, nursing and pharmacy staffs (if applicable), for actions by all clinicians.

3. A mechanism must be established, when clinical justification exists, to allow the physician's order to be carried out as written.

4. A mechanism must be established, to communicate therapeutic interchange substitutions to clinicians by the CRP which may include, but not limited to, phone, email, written notice when TI's occur.

E. Implementation Plan:

The Clinical Services recommendations will be implemented over a 90-day time period with ongoing communication to CSB/BHA Executive Directors and designated medical services leadership.